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DOW CORNING

April 24, 2015

Document Control Office (7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20004

Re: TSCA Section 8(e) Notification of Substantial Risk: Dimethyl, Methylhydrogen Siloxane, Trimethylsiloxo-terminating reaction with Bis-Methallyl Polypropylene Glycol in C4, 1,3-butadiene-free, polymerized, triisobutylene fraction, hydrogenated hydrocarbons

Dear TSCA Section 8(e) Coordinator:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), as interpreted in the TSCA Section 8(e) Policy Statement and Guidance, Fed. Reg 33129 (June 3, 2003) and other Agency guidance, Dow Corning Corporation submits information concerning a repeated dose skin irritation study with Dimethyl, Methylhydrogen Siloxane, Trimethylsiloxo-terminating reaction with Bis-Methallyl Polypropylene Glycol in C4, 1,3-butadiene-free, polymerized, triisobutylene fraction, hydrogenated hydrocarbons.

Chemical Substances

Chemical Abstract Number	Weight Percent	Component Name
93685-81-5	70-90	Hydrocarbons, C4, 1,3-butadiene-free, polymerized, triisobutylene fraction, hydrogenated
1043538-34-6	10-20	Dimethyl, Methylhydrogen Siloxane, Trimethylsiloxo-terminating reaction with Bis-Methallyl Polypropylene Glycol

Study Title

Modified ISO Skin Irritation Study in Rabbits, 8 Day Repeated Exposure

Summary

The test article was evaluated for primary skin irritation in rabbits. This study was conducted in accordance with the guidelines of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. Two 0.5 g portions of the test article covering 25 mm x 25 mm areas and two 25 mm x 25 mm sections of the control article were topically applied to the skin of each of three rabbits and left in place for a 4 hour period on each of 8 consecutive days. The control article was a dry gauze patch. The sites were graded for erythema and edema at 1 hour following patch removal for the 8 dosing days, and at 24, 48 and 72 hours and on days 4 through 14 following removal of the final sample application.

There was very slight to well-defined erythema and very slight to severe edema observed on the skin of the animals treated with the test article. The Primary Irritation Index for the test article was calculated to be 4.2 (Maximum: 8). The irritation lessened but did not resolve for any animals by 14 days following removal of the final sample application. Under the conditions of this study, the response of the test article was categorized as moderate.

Actions

Dow Corning has not made a determination as to whether a significant risk or injury to human health or the environment is actually presented by the findings. Dow Corning Corporation will notify EPA of any further relevant information that may develop concerning this product. If you have any questions concerning this submission, please contact me at (989) 496-1838, l.d.kennan@dowcorning.com, or at the address provided herein.

Sincerely,



Linda Kennan, MS
Vice President, Corporate Stewardship
Dow Corning Corporation

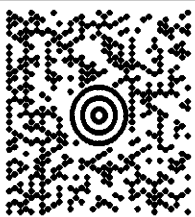

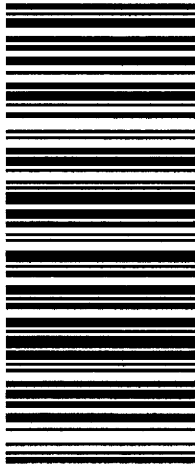

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